

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**

Alexandria Division

COLON HEALTH CENTERS OF)	
AMERICA, LLC, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 1:12-cv-615
)	
BILL HAZEL, in his official)	
capacity as Secretary of)	
Health and Human resources,)	
et al.,)	
)	
Defendants.)	

MEMORANDUM OPINION

THIS MATTER comes before the Court on Plaintiffs' and State Defendants' cross-motions for summary judgment.

Since 1992, Virginia has required purveyors of new medical projects to obtain a Certificate of Public Need (COPN) before conducting business in the state. The application process delays entry into Virginia's medical services market and may cause would-be providers to incur substantial costs. Plaintiffs are out-of-state companies that seek to conduct business in Virginia. They allege Virginia's COPN requirement and application process unconstitutionally discriminate against interstate commerce. Their claim fails because Virginia's COPN laws do not have the purpose or effect of discriminating against

out-of-state businesses, and because they do not unduly burden interstate commerce.

I.

A.

Plaintiff Colon Health Centers of America ("Colon Health") uses computed tomographic ("CT") scanning technology to provide a service called "Integrated Virtual Colonoscopy." Integrated Virtual Colonoscopy is a "one-stop shop" that can screen, diagnose, and treat colorectal cancer during the same appointment. Colon Health believes there is an unmet need for Integrated Virtual Colonoscopy in Virginia; it seeks to provide this service via partnerships with Virginia-based physicians.

Plaintiff Progressive Radiology seeks to operate a specialized magnetic resonance imaging ("MRI") office in Fairfax County, Virginia. The office's radiologists would use an MRI scanner to diagnose injuries to the joints, bones, brain, and spine. Progressive Radiology estimates the Fairfax County office would serve approximately 400 patients per month.

Both plaintiffs are out-of-state providers whose projects are subject to Virginia's COPN requirement. Virginia does not dispute that Plaintiffs' projects would be entirely financed by private funds, nor does it contest whether either plaintiff is qualified to provide the services it seeks to render. Virginia

makes no claim that CT scanning and MRI services are medically controversial.

B.

Virginia is one of 36 states to operate a COPN program. Established in 1973, its program has existed in its current version since a three-year period of deregulation ended in 1992. Virginia requires a COPN for various medical projects, including the "[e]stablishment of a medical care facility" and the "[i]ntroduction into an existing medical care facility of any new...computed tomographic (CT) scanning,...[or] magnetic resonance imaging (MRI) [services]...which the facility has never provided or has not provided in the previous 12 months." Va. Code Ann. § 32.1-102.1(1), (5). While existing medical care facilities must obtain a COPN to operate *additional* CT and MRI scanners, a COPN is not required for *replacement* equipment. § 32.1-102.1(7).

Virginia contains five health planning regions comprised of 22 health planning districts. COPN applications are reviewed in batches, meaning the review process normally does not begin as soon as an application is submitted. Instead, applications gather until the date of a batch review cycle when review of the entire batch begins. § 32.1-102.6(D).

Applications are ultimately evaluated by the State Health Commissioner ("Commissioner"). Prior to the Commissioner's review, however, an informal fact finding conference (IFFC) may

be held in order to further develop the factual record. The Commissioner evaluates eight criteria to determine whether a public need for a project has been demonstrated and a COPN should issue:

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care;

2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by the following: (i) the level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served; (ii) the availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner; (iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6; (iv) any costs and benefits of the project; (v) the financial accessibility of the project to the residents of the area to be served, including indigent residents; and (vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project;

3. The extent to which the application is consistent with the State Medical Facilities Plan;

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served;

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school, and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, an improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Va. Code Ann. § 32.1-102.3.

The Commissioner has 45 days after the close of the record to decide whether a public need has been demonstrated by a COPN applicant, but the Commissioner may extend this period up to 25 additional days, § 32.1-102.6(E), provided the ultimate determination is made

within 190 calendar days of the beginning of the appropriate batch cycle. § 32.1-102.6(D).

Ultimately, the Commissioner will grant or deny each application. Approval may be conditioned on an applicant's agreement to provide care to indigent patients at a reduced rate or accept patients requiring specialized care. If an applicant or another interested person is dissatisfied with the Commissioner's decision, judicial review may be sought under the Virginia Administrative Process Act. § 32.1-24.

C.

On June 5, 2012, Plaintiffs filed a complaint in this Court challenging the constitutionality of Virginia's COPN program. Plaintiffs argued the program violated the "dormant aspect of the Commerce Clause" as well as three provisions of the Fourteenth Amendment. This Court granted Defendants' motion to dismiss for failure to state a claim upon which relief may be granted on September 14, 2012. 2012 WL 4105063.

On appeal, the United States Court of Appeals for the Fourth Circuit affirmed in part, reversed in part, and remanded on October 23, 2013. Colon Health Centers of America, LLC v. Hazel, 733 F.3d 535 (4th Cir. 2013). On remand, the only issue to be decided is whether Virginia's COPN program violated the dormant Commerce Clause.

Following the completion of discovery, both parties move for summary judgment.

II

A.

The Constitution grants Congress power to "regulate Commerce...among the several States[.]" U.S. Const. art. I, § 8. Although the Commerce Clause is an affirmative grant of power to Congress, the Supreme Court "long has recognized that it also limits the power of the States to erect barriers against interstate trade." Lewis v. BT Investment Managers, Inc., 447 U.S. 27, 35, 100 S. Ct. 2009, 2015, 64 L. Ed. 2d 702 (1980); see also Brown v. Hovatter, 561 F.3d 357, 362-63 (4th Cir. 2009) ("the Commerce Clause does more than confer power on the Federal Government; it is also a substantive restriction on permissible state regulation of interstate commerce" (citing Dennis v. Higgins, 498 U.S. 439, 447, 111 S. Ct. 865, 870, 112 L. Ed. 2d 969 (1991))). However, this limit on state power—the "dormant" Commerce Clause—"is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." Maine v. Taylor, 477 U.S. 131, 138, 106 S. Ct. 2440, 2447, 91 L. Ed. 2d 110 (1986).

The Fourth Circuit applies a two-tiered analysis to determine the level of scrutiny it applies to dormant Commerce

Clause challenges. Env'tl. Tech. Council v. Sierra Club, 98 F.3d 774, 785 (4th Cir. 1996). Cases are ultimately decided based on whether the statute a) discriminates against interstate commerce; or b) has an incidental burden on interstate commerce that is "clearly excessive in relation to the putative local benefits." Id. The two levels of scrutiny are not separated by a bright line. Id.

The more demanding level of scrutiny applies where a state law discriminates against interstate commerce "facially, in its practical effect, or in its purpose." Id. In these cases, where the state's action "amounts to simple economic protectionism," a "virtually per se rule of invalidity" applies. Wyoming v. Oklahoma, 502 U.S. 437, 454, 112 S. Ct. 789, 800 (1992) (citing City of Philadelphia v. New Jersey, 437 U.S. 617, 623-24, 98 S. Ct. 2531, 2535 (1978) ("The opinions of the Court through the years have reflected an alertness to the evils of 'economic isolation' and protectionism, while at the same time recognizing that incidental burdens on interstate commerce may be unavoidable when a State legislates to safeguard the health and safety of its people.")). The higher tier of scrutiny applies if a statute discriminates "facially, in its practical effect, or in its purpose." Sierra Club, 98 F.3d at 785. In these cases, the statute will be upheld only if it "serves a legitimate local purpose" that could not be equally served by available

nondiscriminatory means. Taylor, 477 U.S. at 138 (citing Hughes v. Oklahoma, 441 U.S. 322, 336, 99 S. Ct. 1736, 60 L. Ed. 2d 250 (1979)); see also Sierra Club, 98 F.3d at 785 ("In order to survive such scrutiny, the state must prove that the discriminatory law is demonstrably justified by a valid factor unrelated to economic protectionism, and that there are no nondiscriminatory alternatives adequate to preserve the local interests at stake").

More deference will be shown toward state statutes that fall into the second tier; those that merely burden interstate commerce incidentally. Such statutes will be upheld unless "the burdens they impose on interstate trade are clearly excessive in relation to the putative local benefits," Taylor, 477 U.S. at 138 (citing Pike v. Bruce Church, Inc., 397 U.S. 137, 142, 90 S. Ct. 844, 847, 25 L. Ed. 2d 174 (1970)). Application of this level of scrutiny is commonly referred to as the "Pike Balancing Test."

In applying the dormant Commerce Clause, a court must assess the challenged statute's burden on the interstate market as a whole rather than any specific interstate firm. Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 127-28, 98 S. Ct. 2207, 2215, 57 L. Ed. 2d 91 (1978) (citing Hughes, 441 U.S. 322). Moreover, dormant Commerce Clause analysis must not ignore the states' traditional police power. "In determining whether the

state has imposed an undue burden on interstate commerce, it must be borne in mind that the Constitution when conferring upon Congress the regulation of commerce, never intended to cut the States off from legislating on all subjects relating to the health, life, and safety of their citizens, though the legislation might indirectly affect the commerce of the country." Huron Portland Cement Co. v. City of Detroit, Mich., 362 U.S. 440, 443-44, 80 S. Ct. 813, 816 (1960).

B.

Summary judgment is appropriate when a movant demonstrates there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is mandated "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986).

When ruling on motions for summary judgment, the Court must believe the evidence of the non-moving party and construe all reasonable inferences in its favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S. Ct. 2505, 2513, 91 L. Ed. 2d 202 (1986). Still, the "mere existence of some disputed facts" does

not mandate a trial. Thompson Everett, Inc. v. Nat'l Cable Adver., L.P., 57 F.3d 1317, 1323 (4th Cir. 1995). Instead, summary judgment will be granted when the disputed facts are "material to an issue necessary for the proper resolution of the case and the quality and quantity of the evidence offered to create a question of fact [is] adequate to support a jury verdict." Id.

III

A.

The sole issue before the Court is whether the program discriminates against or unduly burdens interstate commerce. When a state exercises its traditional authority to regulate public health, resultant burdens inevitably fall on business ventures that would otherwise operate without legal restraint in an unregulated market. That Virginia's COPN program may make it more difficult for Plaintiffs to enter the Virginia medical services market is insufficient to demonstrate a dormant Commerce Clause violation. See Am. Motors Sales Corp. v. Div. of Motor Vehicles, 592 F.2d 219, 224 (4th Cir. 1979) ("if an adverse effect on competition were, in and of itself, enough to render a state statute invalid, the States' power to engage in economic regulation would be effectively destroyed"). Instead, Plaintiffs must show the COPN requirement, "if enforced, would negatively impact interstate commerce *to a greater degree than*

intrastate commerce." Colon Health Centers, 733 F.3d at 543 (quoting Waste Mgmt. Holdings, Inc. v. Gilmore, 252 F.3d 316, 335 (4th Cir. 2001)).¹

When this case was remanded, the Fourth Circuit directed the parties to focus factual development primarily on the discriminatory effects test. Id. at 546. This Court's analysis will similarly focus on the discriminatory effects test, although Defendants prevail under either the discriminatory effects test or the Pike Balancing Test.

B.

Defendants presented a study by Dr. John W. Mayo, a Professor of Economics, Business and Public Policy at Georgetown University and Executive Director of the Georgetown University Center for Business and Public Policy. He was tasked with determining whether Virginia's COPN program has had a statistically differential burden on out-of-state entities. His study revealed that over a 14-year period ending in January 2014 "approval rates for applications submitted by in-state and by out-of-state firms considered by the Virginia Department of Health have been virtually identical." The approval rate for each was roughly 85 percent.

¹ Plaintiffs do not argue that the challenged statute facially discriminates against interstate commerce or that it was enacted for the purpose of discriminating against interstate commerce. The Court's analysis will therefore be limited to whether Virginia's COPN program has a discriminatory effect.

The parties disagree sharply over how Professor Mayo assessed whether a COPN applicant was an in-state or out-of-state business. Plaintiffs object to his use of an entity's state of incorporation as the determining factor, noting the large number of applicants listing Delaware as their state of incorporation.

Notwithstanding Delaware's disproportionate influence on corporate law, it was plainly reasonable for Professor Mayo to consider an entity's state of incorporation in conducting his analysis. State of incorporation is relevant to whether an entity is an out-of-state business discriminated against by Virginia's regulatory scheme. Plaintiffs adduce no evidence indicating the data are based on Delaware corporations whose principal place of business is in Virginia, that those businesses had their applications granted at a high rate, and that Defendants chose to view the businesses as out-of-state to unfairly enhance the percentage of out-of-state approvals.²

Plaintiffs' contention that Professor Mayo's data are unreliable because the approval rates only account for those applicants that "*successfully weathered the delay, expense, and uncertainty necessary to complete the [COPN] application process*" is similarly unpersuasive. Not only is it a fool's errand to account for every entity that *considered* applying for

² A business incorporated out-of-state with a principal place of business other than Virginia is clearly an out-of-state business.

a COPN but chose not to, there is no reason to believe abandoned application ideations occur at different rates in out-of-state companies than in in-state companies. Data concerning businesses that submitted letters of intent but failed to apply are of little value for the same reason: there is no evidence indicating the burdens of the COPN application process, rather than another of the myriad reasons why applicants fail to follow-through, caused these would-be applicants to abandon their plans.

Rather than produce conflicting data indicating Virginia's COPN program indeed *does* have a discriminatory effect on interstate commerce, Plaintiffs instead offer their own anecdotal testimony of why the program's requirements make application unworkable for them. In doing so, Plaintiffs raise an as-applied challenge to Virginia's COPN statute. The dormant Commerce Clause, however, "protects the interstate market, *not particular interstate firms*, from prohibitive or burdensome regulations." Exxon, 437 U.S. at 127-28 (emphasis added); see also Colon Health Centers, 733 F.3d at 543. Thus, Plaintiffs' as-applied challenge fails.

Plaintiffs' assert that once a COPN application is approved, the applicant becomes an "insider" regardless of whether it was in-state or out-of-state when it first applied for a COPN. This reasoning is circular and unpersuasive. Under

Plaintiffs' theory, the COPN requirement discriminates against out-of-state entities until a COPN is approved, at which point the same statute begins to discriminate in their favor. Clearly, successful applicants all operate medical projects inside Virginia. It is impossible to determine whether the COPN program discriminates against interstate commerce if the data treat successful applicants as in-state entities *ab initio*. Under Plaintiffs' view, the success rate of new out-of-state applicants should be measured against the success rate of new in-state applicants *combined with every previously-successful entity currently operating in Virginia*. This approach tips the scales in favor of new out-of-state applicants; it does not provide an accurate depiction of whether Virginia's COPN program discriminates against interstate commerce.

While replacement of existing medical equipment does not require a new or updated COPN, an existing medical care facility must apply for a new COPN in order to add equipment to its practice. Va. Code Ann. § 32.1-102.1(7). This evenhanded approach supports the credibility of Virginia's guiding principles for its COPN program. See 12 Va. Admin. Code § 5-230-30. Businesses that sell replacement equipment to existing medical care facilities that have already established a public need for their services face a less onerous bureaucratic path forward than businesses that seek to establish new medical

projects. This is true for both in-state and out-of-state entities.

Plaintiffs have not produced evidence indicating Virginia's COPN program discriminates against interstate commerce. The mere fact that the COPN requirement discouraged Plaintiffs from doing business in Virginia does not permit striking down an entire regulatory program—or any portion of it—as unconstitutional.

C.

Defendants' err in their assertion that the Pike balancing test does not apply here. Although the Fourth Circuit focused the parties on the discriminatory effects test, Colon Health Centers, 733 F.3d at 546, it also held it was error to dismiss Plaintiffs' Pike claim. Id. In short, if the statute's incidental burden on interstate commerce clearly exceeds its putative local benefits, it must be struck down.

Application of the Pike balancing test in this case is straightforward. Virginia is one of 36 states to have some form of medical certificate-of-need requirement, and its putative local benefits—improving medical quality by ensuring adequate patient volume, facilitating indigent care, improving the state's economy, and providing cost benefits—are neither speculative nor rare. Further, the burdens of Virginia's program do not fall predominantly on out-of-state interests, see Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc., 401 F.3d 560, 569

(4th Cir. 2005), as the regulatory scheme applies evenhandedly to in-state and out-of-state entities.

To survive scrutiny under the Pike balancing test, Defendants are not required to prove their COPN program is the ideal bureaucratic regime to achieve its stated goals. Instead, they must assert local benefits that outweigh the statute's burden on interstate commerce—a form of rational basis review—and here, the putative local benefits are clear. Evidence elicited during discovery indicates a) there is a generally accepted correlation between quantity and quality in health care; b) the COPN program contributes significantly to the burden of indigent care in Virginia; and c) the COPN program likely generates a modest reduction in acute care spending. In sum, the program places minimal burdens on interstate commerce and promotes legitimate local benefits; therefore it must be sustained under the Pike Balancing Test.

The Virginia COPN statute does not have a discriminatory effect on interstate commerce and any burden it imposes on interstate commerce does not outweigh its putative local benefits. Because there are no genuine issues of material fact, Defendants are entitled to judgment as a matter of law.

An appropriate order shall issue.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
October 23, 2014